



4-1-03

16424

Patent Docket P0998D2

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

P#17

In re Application of Jeffrey L. Cleland et al. Serial No.: 09/648,896 Filed: August 25, 2000 For: PROTEIN FORMULATION	Group Art Unit: 1642 Examiner: Christopher Yaen  Express Mail No. EL 809 449 235 US <u>March 31</u> , 2003 <u>Wm Lee</u> Wendy M. Lee
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**RECEIVED**Assistant Commissioner of Patents  
Washington, D.C. 20231

APR 08 2003

TECH CENTER 1600/2000

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR § 1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

- ☐ **37 CFR § 1.97(b)**
- within three months of the filing date of the application other than a continued prosecution application under 37 CFR § 1.53(d); **or**
  - within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491, **or**
  - before the mailing of the first Office action on the merits; **or**
  - before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR § 1.114.
- ☒ **37 CFR § 1.97(c)**
- by the applicant after the period specified in 37 CFR § 1.97(b), but prior to the mailing date of any of a final action under 37 CFR § 1.113, or a notice of allowance under 37 CFR § 1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR § 1.17(p) **or** a statement as specified in 37 CFR § 1.97(e), as checked below.
- ☐ **37 CFR § 1.97(d)**
- after the period specified in CFR § 1.97(c), and is accompanied by the fee set

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forth in 37 CFR § 1.17(p) **and** a statement as specified in 37 CFR § 1.97(e), as checked below.

[If either of boxes 37 CFR § 1.97(c) or 37 CFR § 1.97(d) is checked above, the following statement under 37 CFR § 1.97(e) may need to be completed.]

- ☐ **37 CFR § 1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR § 1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR § 1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR § 1.704.
- ☒ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR § 1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC § 120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-() " (nucleotide) and "BLAST Results B-1 - B-() " (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☒ [X] not given
- ☐ [] given for each listed item
- ☐ [] given for only non-English language listed item(s) [Required]
- ☐ [] in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,  
GENENTECH, INC.

Date: March 31, 2003

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PATENT TRADEMARK OFFICE

U.S. Dept. of Commerce  
Patent and Trademark Office

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Applicant  
Cleland et al.

Filing Date  
25 Aug 2000

Group  
1642

301 Chang et al., "Surface-induced denaturation of proteins during freezing and its inhibition by  
surfactants" Journal of Pharmaceutical Sciences 85(12):1325-1330 (Dec 1996)

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